INNOVATIVE INTEGRATION AND USE OF WELL-KNOWN INFORMATION TECHNOLOGY TOOLS TO SUPPORT THE MANAGEMENT OF ISO QUALITY AND ENVIRONMENTAL STANDARDS IN A CLINICAL LABORATORY

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ABSTRACT

The use and implementation of Information Technology (IT) systems to support ISO-based certifications is essential to provide effective ways of communicating, controlling and updating information. They can ensure an adequate workflow for documentation, nonconformities, preventive actions and continual improvement reports and also gather statistical data for monitoring the performance of the system. The objective of this work is to present innovative applications of IT systems developed in-house to support the ISO-based Quality and Environmental Management Systems at Fleury Diagnostics, a large reference laboratory in Brazil. We developed and implemented a user-friendly, online electronic system using well-known software and computer interface tools based on the Microsoft platform (Word, Outlook, Internet Explorer, Windows NT, SQL/Server, IIS, ASP and Visual Basic). The system was developed during three months and validated for 10 months. It was designed to create and register SOPs, non-conformities, preventive actions and continual improvement reports and assure their traceability. All documents and reports are available in an Intranet System that can be accessed by all employees. This same system was used to publish environmental aspects and impacts and monitor environmental programs. Easy and fast training was provided for all employees. Educational materials are available through the same user interface. An internal electronic administrator module allows authorized personnel to control the entire system. This application is currently managing 1,100 SOP's, 182 environmental aspects, 33 environmental programs. About 3,000 nonconformities reports have been registered since 1999. The implementation of an online, paperless, electronic system was essential to support the management of ISO standards. Besides being a user-friendly and reliable system, the cost for implementation was low. The internal development allows quick customization and updating and complies with the requirements of certification and accreditation agencies. The paperless approach was also useful for reducing paper usage, contributing to achieve the environmental goals of the laboratory.

Fleury Diagnostics is a large reference laboratory in Brazil, with distant sites integrated via broadband Intranet. The laboratory has been ISO 9001-certified since 1999, and it implemented in 2002 an Integrated Management System (IMS) based on ISO 9001:2000 (Quality Management System) and ISO 14001:1996 (Environmental Management System). Both certifications have a high demand for documentation. To meet this demand, a document management system is needed, and most institutions have paper-based systems. At Fleury, we opted for a paperless one. The objective of this work is to present innovative applications of IT systems developed in-house to support the ISO-based certifications in the clinical laboratory.

ISO (International Organization for Standardization) is a non-governmental organization and one the most important developers of international standards. It is composed of members from international institutes of more than a hundred countries and its central office is in Geneva, Switzerland. The standards elaborated by ISO are intended to be applicable to industrial and business organizations of all sizes and types. Its main purpose is to develop standards internationally recognized, contributing to make the development, manufacturing and supply of products and services more efficient, safer and cleaner. The ISO 9001:2000 – "Quality Management System – Requirements" presents requirements to the implementation of quality management systems, while the ISO14001: 1996 - "Environmental management systems - Requirements with guidance for use" provides organizations with tools to implement efficient environmental management systems, making them able to achieve financial goals in a sustainable way.

Control of records and documentation is a very important requirement of both standards. Examples of documents required by ISO are:

- Quality / Environmental Manuals
- SOP's
- Non-conformity Reports (Corrective actions)
- Preventive Actions
- Continual Improvement Reports
- Environmental aspects and impacts
- Environmental Programs, etc.

International Organization for Standardization

The main requirements related to control of documents for ISO 9001 and ISO 14001 are shown in Table 1.

Documentation
Documents are elaborated and approved by authorized personnel, before they are available to the users
Documents are periodically analyzed and, if necessary, revised and updated
The revised parts of a document are identified
There is a revision control, and only the updated versions are available to the users
Obsolete documents are removed from all points when a new version is published
Obsolete documents that need to be kept in the laboratory are identified properly to avoid unintended use
External documents that can affect the performance of the processes (equipment manual, bibliographic references, guidelines and standards, legal requirements, etc.) are controlled and updated, when necessary

Table 1: Control of Documents – Requirements

Clinical laboratories usually apply a lot of effort to achieve compliance to these requirements, specially with paper-based systems. The system developed at Fleury to control the ISO documentation was designed to fulfill the following needs:

- Internal development by our Information Techno-logy (IT) team
- Fully based on the Microsoft Platform, which was already widely used in our Intranet
- Full electronic control of elaboration and maintenance of a document, including the traceability of the entire process
- Totally paperless

Based on these requirements, the system was designed and validated during a 3-month period and then placed in operation. The system was created using the Microsoft platform (Word, Outlook, Internet Explorer, Windows NT, SQL/Server, IIS, ASP and Visual Basic). Its development was divided in three components:

1. Creating and modifying documents
2. Accessing documents
3. Managing documents

The 1st component allowed us to automate the creation of documents by using templates from MS Word. The entire process of document elaboration, revision and approval uses Outlook/SQL server and, when a document is modified, the version is automatically controlled by highlighting the modifications. Office assistant messages are used to help the user in all steps of the process.

The 2nd component assures easy access to the document in our Intranet, via MS Internet Explorer. This tool allows access only to the last version of approved documents, and enables the search for a specific document according to the lab section or its description. Previous versions or documents before approval cannot be accessed by the end-user, because they are kept in a different database, accessible only to specific, password-authorized users. Users can also know all details about a document or version, including who was responsible for consensus and approval, and also check the status of a new version of a document, including who is holding the electronic version in a specific moment.

The 3rd component allows full management of documents and the system, with access restricted to the ISO System coordinators. It is also capable of creating reports. A flow chart summarizing the process of documents elaboration is shown in Figure 1.

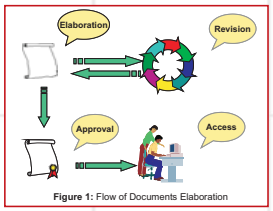

Figure 1: Flow of Documents Elaboration

The main steps for elaborating, accessing and managing a document are shown in Figures 2 to 10

Figure 2: The document is created using templates from Word. The user access is controlled by his/her Intranet login

Figure 3: After the document is created by the author, it must be sent to at least two reviewers

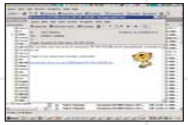

Figure 4: Reviewers receive automatically by e-mail a shortcut to the document. All changes made by reviewers are marked in a different color.

Figure 5: After all changes are made, the document must be sent for approval. If any other change must be made, the document is sent back to the author. Otherwise, the approver identifies the reason for creating the document, for traceability purposes

Figure 6: After approval, the author receives an e-mail to send the link of the document for training of all pertinent departments and employees

Figure 7: Once approved, the document can be easily accessed in the Intranet

Figure 8: The new version of the document is immediately available for access in the Intranet. The old version is moved to another database and it can be accessed by the system administrators at any time

Figure 9: Not only the document is available in the Intranet, but also the information about the elaboration process, for traceability purposes

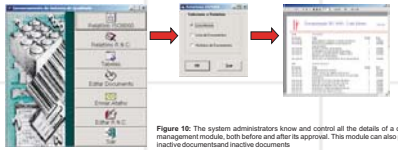

Figure 10: The system administrators know and control all the details of a document version through the system's management module, both before and after its approval. This module can also provide detailed reports on all active and inactive documentsand inactive documents

Non-conformity reports can also be created and managed by using the system, as shown in Figures 11 to 13.

Figure 11: Non-conformity reports are created using the same system. The team responsible for filling an specific non-conformity report receives a shortcut by e-mail to access and fill them out.

Figure 12: Non-conformity reports are also available online for Intranet access

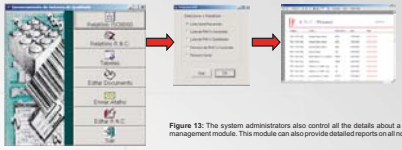

Figure 13: The system administrators also control all the details about a non-conformity report using the system's management module. This module can also provide detailed reports on all non-conformities.

Continual Improvement Reports, Environmental Aspects and Impacts and Environmental Programs are also available in the Intranet, as seen in Figures 14, 15 and 16 .

Figure 14: Continual Improvement Report

Figure 15: Environmental Aspects and Impacts Chart

Figure 16: Environmental Program

This system is currently managing 1,031 documents and more than 3,000 non-conformity reports opened since 1999.

285 environmental aspects and impacts as well as 33 environmental programs are also available in the Intranet and accessible to all employees.

Educational material can also be accessed by employees to refresh their knowledge about the Quality and Environmental Systems. Examples are given in Figure 17.

Figure 17: Examples of online educational materials

The implementation of an online, paperless, electronic system was essential to support the management of ISO standards. We have been successfully utilizing this online, electronic document management system in our laboratory for 6 years, and it has proven to be very reliable and user-friendly. So, by using well-known software tools, and wisely integrating them into this system, we were able to solve the bottleneck of document management for certification programs. This has been accomplished at low cost – half of the price of an off-the-shelf system - and, very importantly, with easy and fast training to use it, because all user interfaces were based in the widely known Microsoft platforms. Besides, the internal development allows quick customization and updating in order to improve its performance. The paperless approach was also useful for reducing paper usage, contributing to achieve the environmental goals of the laboratory.

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